

Application No. 10/674,750  
Amendment Dated August 3, 2005  
Reply to the Final Rejection in the Office Action of April 20, 2005

### **REMARKS**

In the Office Action dated April 20, 2005, claims 15-31 were examined with the result that all claims were rejected. The Examiner made the rejection final. In response, Applicant has filed a Request for Continuing Examination (RCE) and this Amendment which has canceled claims 15-19 and 31, and rewritten claims 20-22 and 30. In view of the above amendments and following remarks, reconsideration of this application is requested.

Applicant first notes that a Substitute Power of Attorney was filed along with the Amendment After Final Rejection dated June 16, 2005 yet the Advisory Action of July 13, 2005 was mailed to Applicant's predecessor law firm. Applicant respectfully requests entry of the Substitute Power of Attorney in order to expedite prosecution of this application. Another copy of the Substitute Power is enclosed for the convenience of the Examiner.

On page 2 of the Office Action, the Examiner objected to the disclosure stating that although various trademarks have been capitalized, they appear not to be accompanied by the generic terminology for the marks. Accordingly, Applicant has revised the description and inserted generic terminology for each identified product. In some cases, the terms referred to by the Examiner were being utilized merely as company names, and in those locations, Applicant has corrected the description to indicate that the marks are not being utilized as trademarks for a product, but instead as the name of a company from which such products could be obtained. Applicant believes it has corrected all of the trademark descriptions noted by the Examiner on page 2 of the Office Action, and accordingly, requests the Examiner withdraw the objection to the description issued on this basis.

On page 3 of the Office Action, the Examiner rejected claims 1-3 and 5-13 under §112, first paragraph. However, Applicant believes this rejection must be in error as claims 1-3 and 5-13 were previously canceled. Thus, Applicant believes this rejection is moot.

At the bottom of page 3 of the Office Action, the Examiner rejected claims 15-18 under 35 USC §102(b) as being anticipated by Bush et al. In response, Applicant has canceled claims 15-18 via the present Amendment. Accordingly, Applicant believes this rejection is now moot.

At the top of page 6 of the Office Action, the Examiner objected to the brief description of the drawings as being improper. In response, Applicant has submitted a revision to the description which describes each Figure with a new sentence. Applicant has proposed inserting these new descriptions at page 3 of the specification as filed, and then inserting a new heading entitled "Detailed Description of the Invention" and thereafter retaining the previous descriptions of the drawings. It appeared to Applicant that this would be a "cleaner" way of overcoming the Examiner's objection, rather than attempting to modify the paragraphs originally discussing the drawings. Obviously, by doing this, those original paragraphs become part of the "Detailed Description of the Invention" section of the application. Thus, Applicant requests approval of the current addition of the Description of the Drawings as none of this material would be considered new matter. In light of this modification to the Description, Applicant requests the Examiner withdraw the objection to the drawings.

On page 6 of the Office Action, the Examiner also rejected claim 30 under 35 USC §112, first paragraph as failing to comply with the written description requirement. The Examiner has objected to claim 30 stating that the claims are drawn to a genus of polypeptides that are not adequately defined in the specification as filed.

In response, however, Applicant notes that claim 30 is not claiming or drawn to a genus of polypeptides. Instead, the claim is drawn to a "method for the detection of a disorder" and now sets forth nine steps for detecting those disorders. The Examiner believes that polypeptides such as "prion protein fragments", "beta protein fragment" and the like are not accurately described. However, it is important to note that complete or partial structures of such fragments, physical and/or chemical properties, and methods of making these fragments are all well known to those skilled in the art and most

importantly, their structures, properties, function and the like are not necessary to being able to perform the steps of the present invention as defined in claim 30. In other words, one of the steps of claim 30 is to contact proteons produced in a subsample with an antibody that binds to various listed proteins. It is not necessary to define the specific prion protein fragment, beta protein fragment, etc. because one skilled in the art would recognize that the step involves binding an antibody to such fragment, irregardless of the structure, properties, and/or functions of said fragments. Thus, Applicant is not claiming a genus of polypeptides, but instead is claiming the step of contacting proteons in a subsample to an antibody that binds to any one of those polypeptides. Again, one skilled in the art would readily recognize that no matter what the structure, property or function of said fragments might be, it is the step of antibody binding to that fragment that is important to claim 30. Thus, Applicant believes claim 30 does adequately claim the invention in sufficient detail so that one skilled in the art would be able to practice the invention of claim 30.

At page 8 of the Office Action, claims 30-31 were rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. The Examiner believes undue experimentation would be required to practice the invention of claims 30-31. The Examiner thus believes the Applicant has not shown how the method of the invention can be used to detect disorders.

In response, Applicant has amended claim 30 to call for the specific steps of contacting the proteons produced in a subsample with an antibody that binds to a protein, identifying the protein, and correlating the identified protein to a disorder. These latter disorders were originally defined in claim 31 and have now been incorporated into claim 30 which necessitated the cancellation of claim 31. Thus, claim 30 now specifies all of the steps necessary to show how the method of the invention can be used to detect disorders. As stated in Applicant's description, it is well known by those skilled in the art that certain proteins correlate to certain disorders. In view of this knowledge, once the protein bound in the subsample is identified, one can readily correlate the identified

protein to a particular disorder, or at least eliminate particular disorders. For example, Applicant submits herewith four of the articles referred to in the description at the top of page 7. These articles clearly evidence the fact that it is well known in the art that the identification of various proteons is indicative of a disorder or disease state. Thus, Applicant believes it is not necessary to provide extensive examples on how the identification of various proteins correlate to the detection of various disorders. These steps are well known to those skilled in the art. Thus, Applicant believes the Examiner should withdraw the §112 rejection based on enablement.

On page 12 of the Office Action, the Examiner objected to claims 21-32 under 35 USC §112, second paragraph, as being indefinite. With regard to claims 21-29, the Examiner indicated that claim 21, although claiming a method of cyclic amplification of proteons, did not have an end point specified. Accordingly, Applicant has rewritten claim 21 to call for heating the subsample, then determining the number of proteons in the sample, and finally, repeating the first three steps until the number of proteons determined to be in each heated subsample no longer increases. Applicant believes this adequately provides an end point to the method of claim 21. Also, the amendments to claim 21 are not new matter as they are clearly set forth in the description as filed.

At the top of page 13 of the Office Action, the Examiner objected to claims 22-29 under 35 USC §112, second paragraph, as once again not providing a clear end point. In response, Applicant notes that in view of the amendment to claim 21, claim 22 has been revised to merely state the additional step of correlating the number of proteons in the subsample to the number of misfolded proteins present in the sample. This step of correlation is predictive of the progress of a disease. Support can be found in the specification as filed at page 6, lines 17-26.

Also at the top of page 14 of the Office Action, claims 30-31 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to provide a clear end point to the method. In response, as noted previously herein, claim 30 has been amended to add the steps of identifying the protein, and correlating the identified protein to a

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disorder. As a result, Applicant believes claim 30 now has a definite end point and adequately describes how the method for the detection of a disorder is accomplished. Thus, Applicant believes the Examiner should withdraw the objection to original claims 30-31.

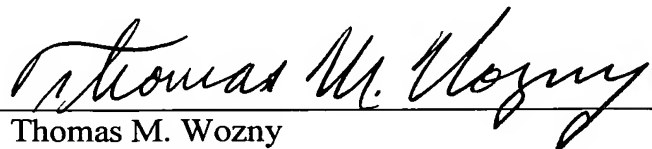
Finally, Applicant notes that although original claim 20 has been rejected by the Examiner, there is no specific discussion of claim 20 anywhere in the Office Action. In the previous Office Action dated August 10, 2004, claim 20 was "objected to," but once again, was not specifically discussed in the Office Action. Applicant believes claim 20 is distinguishable over the prior art as none of the prior art discusses or teaches the clearing of misfolded proteins from blood. The Examiner should note that Applicant has attempted to revise claim 20 so that it is definite and provides a clear end point. This was merely an attempt to avoid an anticipated §112, second paragraph, rejection. However, claim 20 now clearly states that a blood sample is contacted with a protein nucleation center for a period of time, and thereafter, the misfolded proteins are removed from the sample. Applicant believes claim 20 is now allowable, and respectfully requests the same herein.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Vitaly J. Vodyanoy, et al

Appln. No. 10/674,750

Filed: September 30, 2003

) Group Art Unit: 1653

) Examiner: Robert B. Mondesi

) METHOD OF ISOLATION AND SELF-  
) ASSEMBLY OF SMALL PROTEIN PARTICLES  
) FROM BLOOD AND OTHER BIOLOGICAL  
) MATERIALS

SUBSTITUTE POWER OF ATTORNEY

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Alexandria, VA 22313-1450

Sir:

The undersigned AUBURN UNIVERSITY is the owner of the above identified U.S. patent application by virtue of an assignment dated 1/12/2004 and recorded in the USPTO on 2/17/2004 at Reel 014343, Frames 0753-0756.


The undersigned hereby revokes all previous powers of attorney and appoints the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office threewith:

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